MAY 2 6 2000

K000215

EMS Engineered Medical Systems ISO 9001 Certified

2055 EXECUTIVE DRIVE • INDIANAPOLIS, IN 46241 • (317) 246-5500 • FAX (317) 246-5501

Non-Confidential Summary of Safety and Effectiveness

January 21, 2000

Engineered Medical Systems, Inc.
2055 Executive Rd.
Indianapolis, IN 46241

Tel - (317) 246-5500

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Official Contact:	Bonnie Holly - Manager QA
Proprietary or Trade Name:	EMS Swivel Elbow
Common/Usual Name:	Exhalation Port
Classification Name:	Breathing attachment - positive end expiratory pressure
Device:	EMS Swivel Elbow
Predicate Devices:	Respironics - Whisper Swivel II - K962203

Device Description:

The intended device is a three (3) part assembly which connects between the face mask and the circuit hose. It is designed to swivel and has a series of fixed holes which provide the continuous leak path. The EMS Swivel Elbow is intended to be a substitute for the Respironics Whisper Swivel II and thus utilized in all Respironics - CPAP or Bi-level systems as well as supplied an accessory in the patient circuit.

Intended Use:

Indicated Use --	To provide a continuous leak path in the patient circuit, exhalation port. The EMS Swivel Elbow is used with and attached to a positive pressure air source, CPAP or Bi-level equipment, and has the Indications for Use consistent with the Indications for Use of the equipment to which it is attached.
Environment of Use --	Hospital, sleep laboratories or home

Comparison to Predicate Devices:

Attribute	Intended device Swivel Elbow	Respironics Whisper Swivel II
Use		
Intended Use -- in circuits for use in Adult Obstructive Sleep Apnea (OSA)	Yes	Yes
Intended equipment - to be used with devices - CPAP and Bi-level systems	Yes	Yes
Intended equipment - to be used with Respironics - REMstar CPAP or Bi-level systems	Yes	Yes
Intended Environment - Hospital, Home and Sleep labs	Yes	Yes
Design		
Provides a continuous leak path in circuit	Yes	Yes
Placed in patient circuit near patient's face	Yes	Yes
Made to be cleaned	Yes	Yes
Provided non-sterile	Yes	Yes
Reusable - multi-use	Yes	Yes
Materials - polycarbonate	Yes	Yes
Performance Standards/Specifications		
Equivalent flow (leak) rate vs. pressure compared to predicates	Yes	N/A
Meets design requirements after cleaning	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices

There is no significant difference between the intended device and the predicate, Whisper Swivel II cleared under K962203.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2000

Ms. Bonnie Holly
Engineered Medical Systems
2055 Executive Drive
Indianapolis, IN 46241

Re: K000215
Swivel Elbow
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: April 24, 2000
Received: April 26, 2000

Dear Ms. Holly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Brian E. Hamerman for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2

INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: _____ (to be assigned)

Device Name: EMS Swivel Elbow

Intended Use: To provide a continuous leak path in the patient circuit, exhalation port. The EMS Swivel Elbow is used with and attached to a positive pressure air source, CPAP or Bi-level equipment, and has the Indications for Use consistent with the Indications for Use of the equipment to which it is attached.

Environment of use: Hospital, sleep laboratories or home

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000215

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)